K052870

PREMARKET NOTIFICATION (510(K)) SUMMARY

SEP 29 2006

Submitted by:	Kimberly-Clark Corporation 1400 Holcomb Bridge Road Roswell, GA 30076 USA Tel: 770-587-8000
Contact Person:	Tierney Norsted Ph.D., M.P.H. Exec Vice President, Principal Advisor Regulatory & Clinical Research Institute, Inc. 5353 Wayzata Blvd., Suite 505 Minneapolis, Minnesota 55416 952-746-8021 tnorsted@rcri-inc.com
Date of Summary:	September 14, 2006
Device Trade Name:	INTEGUSEAL Microbial Sealant
Common or Usual Name:	Surgical Drape Accessory
Classification Name:	878.4370 Surgical Drape Accessory
Predicate Device(s):	Medical Development Concepts ACTI-Gard Antimicrobial Film (K000442)
Device Description:	INTEGUSEAL Microbial Sealant is a film-forming cyanoacrylate-based product provided in a ready-to-use applicator. The Sealant is intended to be applied on the skin over commonly used surgical skin preparation products with standard surgical draping prior to a surgical incision. Upon polymerization, INTEGUSEAL bonds to the skin, immobilizing the bacteria and thereby reducing the risk of skin flora contamination throughout a surgical procedure.
Indication for Use:	INTEGUSEAL Microbial Sealant is intended for use after typical preoperative skin preparations, with standard surgical draping, and prior to a surgical incision. The product is used to reduce the risk of skin flora contamination throughout a surgical procedure.
Substantial Equivalence:	INTEGUSEAL is substantially equivalent to Medical Concepts Development ACTI-Gard Antimicrobial Film. Both products are placed on the skin following the application of standard surgical skin preparation products and prior to surgical incision and are intended to reduce the risk of skin flora contamination throughout a surgical procedure.
Substantial Equivalence Testing Summary:	Testing demonstrating the substantial equivalence of INTEGUSEAL to ACTI-Gard included *in vitro* microbial and other barrier testing as well as *in vivo* surgical incision microbial contamination testing.
Other Testing Summary:	Significant testing was performed to demonstrate that INTEGUSEAL is compatible with various surgical circumstances, including: ▪ Is compatible with standard skin preparation products and with incise drapes ▪ Is compatible with various surgical materials, tools and techniques, including electro-surgical and defibrillation procedures ▪ Is compatible with various incisional closure techniques and products, including wound closure adhesion strips

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 9 2006

Medlogic Global, Limited
C/O Dr. Tierney Norsted
Executive Vice-President
Regulatory & Clinical Research Institute, Incorporated
5353 Wayzata Boulevard, Suite 505
Minneapolis, Minnesota 55416-1334

Re: K052870
Trade/Device Name: Integuseal Microbial Sealant
Regulation Number: 878.4370
Regulation Name: Surgical Drape and Drape Accessories
Regulatory Class: II
Product Code: NZP
Dated: August 3, 2006
Received: August 4, 2006

Dear Dr. Norsted:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K052870

Device Name: Integuseal Microbial Sealant

Indications For Use: Integuseal Microbial Sealant is intended for use after typical preoperative skin preparations, with standard surgical draping, and prior to a surgical incision. The product is used to reduce the risk of skin flora contamination throughout a surgical procedure.

Prescription Use _____ AND/OR Over-The-Counter Use ___X___
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Sign-Off) 9/29/06
...n of Anesthesiology, General Hospital,
...ion Control, Dental Devices
...) Number: K052870